K092637

## 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date: July 31, 2009

SEP 24 2009

1. Company and Correspondent making the submission:
   Name: Sonomed Inc.
   Address: 1979 Marcus Ave
   Lake Success, NY, 11798
   U.S.A.
   Telephone: 516-354-0900
   Fax: 516-354
   Website: www.sonomed.com
   Contact: Mr. Charles C. O'Neal, Quality Manager
   E-mail: coneal@escalonmed.com

2. Device:
   Trade/proprietary name: PacScan Plus
   Common Name: Diagnostic ultrasound system
   Classification Name: System, imaging, pulsed echo, ultrasonic

3. Predicate Devices:
   Manufacturer: Sonomed, Inc.
   Device: 4000P Pachymeter System
   510(k) Number: 123

   Manufacturer: Sonomed, Inc.
   Device: E-Z Scan 5500+ A-Scan / B-Scan System
   510(k) Number: 123

4. Classification Names & Citations:
   Classification: Class 2
   Classification Code: 21CFR 892.1560, 1570, IYO, ITX, system, imaging, pulsed echo, ultrasonic,

5. Description:
   The PacScan™ Plus is the latest generation ophthalmic biometry instrument introduced by industry leading Sonomed. The series consists of two different models:
   - ***PacScan™ 300A+***. This A-scan system allows for measuring the axial length (AXL), anterior chamber depth, and lens thickness of an eye and for calculating the associated IOL power for an implanted lens.
   - ***PacScan™ 300AP+***. This system seamlessly integrates the A-Scan and Pachymeter capabilities into a single system.

   All systems utilize a high-resolution, color backlit touch screen liquid crystal display (LCD) by which the user can enter information and view data and calculations. Each system

also includes a built-in thermal printer. The system is compact and lightweight thereby making the system extremely portable.

6. Indications for Use:
   The PacScan Plus is Sonomed's newest diagnostic ultrasound system which integrates a contact A-scan system, pachymeter, and analog thermal printer into a single unit for the convenient collection and retention of intraocular measurements. The system's principal application is to serve as an aid in the calculation of the associated IOL power for implanted lenses. As such, the PacScan Plus has been designed to capture key measurements such as axial length, anterior chamber depth and corneal thickness with both accuracy and precision.

7. Comparison with predicate device:
   Sonomed, Inc. believes that the technologies incorporated into the PacScan Plus are substantially equivalent to those of the 4000P pachymeter system and the E-Z Scan 5500+ A-scan / B-scan system.

8. Safety, EMC and Performance Data:
   Electrical, mechanical, environments safety and performance testing according to **standard IEC 60601-1 and IEC 60601-2-37are currently pending and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All tests results were satisfactory.**

9. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification Sonomed, Inc. concluded that the PacScan Plus is safe and effective and substantially equivalent to predicate devices as described herein.

10. Sonomed Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Charles C. O'Neal
Quality Manager
Sonomed, Inc.
1979 Marcus Ave., Suite 105C
LAKE SUCCESS NY 11042

SEP 24 2009

Re: K092637
Trade/Device Name: PAC Scan Plus
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: August 5, 2009
Received: August 27, 2009

Mr. O'Neal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the PAC Scan Plus, as described in your premarket notification:

Transducer Model Number

A-Mode and Pachymeter

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean

that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

## Section 6 – Indications for Use

510(k) Number (if known): K092637

### Indications for Use

Device Name: Pac Scan Plus

Indication for Use:
The PacScan Plus is Sonomed's newest diagnostic ultrasound system which integrates a contact A-scan system, pachymeter, and analog thermal printer into a single unit for the convenient collection and retention of intraocular measurements. The system's principal application is to serve as an aid in the calculation of the associated IOL power for implanted lenses. As such, the PacScan Plus has been designed to capture key measurements such as axial length, anterior chamber depth and corneal thickness with both accuracy and precision.

| Clinical Application | | | | | | Mode of Operation | | |
|---|---|---|---|---|---|---|---|---|
| General (Track 1 Only) | Specific (Tracks 1 & 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic | Ophthalmic | | | | | | | A-Mode and Pachymeter |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Specify) | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Specify) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (Specify) | | | | | | | |

| Prescription Use _____ (21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k)_____



(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092637